



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1295]

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification

Products; Draft Guidance for Industry and Food and Drug Administration Staff;

Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.” This draft guidance clarifies the distinction between hearing aids and personal sound amplification products (PSAPs), as well as the regulatory controls that apply to each. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products” to the Division of Small Manufacturers, International, and

Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Eric A. Mann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2438, Silver Spring, MD 20993-0002, 301-796-5620.

SUPPLEMENTARY INFORMATION:

I. Background

Since issuance of the February 25, 2009 guidance entitled, “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products” FDA has become aware of a lack of clarity regarding how the Agency defines a hearing aid versus a personal sound amplification product (PSAP), which has also led, in some cases, to inappropriate application of regulatory requirements for such products. These inconsistent interpretations of the definitions may inadvertently result in hearing-impaired consumers bypassing safeguards that were implemented to promote the prompt diagnosis of treatable medical conditions causing hearing loss. To ensure consistent

interpretation, consistent application of relevant regulatory requirements, and adequate protection of the public health, FDA seeks to further clarify the definitions of hearing aids and PSAPs.

This draft guidance, when finalized, will supersede the guidance entitled “Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” dated February 25, 2009.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on the definitions and regulatory requirements for hearing aids and PSAPs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products” you may either send an e-mail request to ds mica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1832 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; and the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: November 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.